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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,412	07/25/2001	Jacob Bar-Tana	23117-0002 DIV 1	8876

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EXAMINER	
WHITE, EVERETT NMN	
ART UNIT	**PAPER NUMBER**
1623	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/915,412	BAR-TANA, JACOB	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 21-31* is/are pending in the application.

4a) Of the above claim(s) *21-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-9, drawn to a pharmaceutical composition, classified in class 562, subclass 400 plus.

   II. Claims 21-28, drawn to a method of modulating HNF-4 transcriptional activity in vivo, classified in class 530, subclass 387.1 plus.

   III. Claims 29-31, drawn to a method of treatment of various disorders or diseases, classified in class 514, subclass 825 plus.

The inventions are distinct, each from the other because of the following reasons:

Invention I is unrelated to the inventions of II and III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions since there is no indication in the claims that the pharmaceutical composition of the claims of Group I can be used to modulate the HNF-4 activity in vivo as set forth in the claims of Group II and to treat the disorders or diseases by inhibiting HNF-4 controlled transcription independently of PPARα activation as set forth in Group III.

Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention III has separate utility such as the treatment of coronary or peripheral atherosclerosis and rheumatoid arthritis or multiple sclerosis which are all distinct diseases, which requires different modes of operation for there treatments. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the search required for one Group is not required for the other Groups, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. William Schmonsees on August 22, 2002 a provisional election was made without traverse to prosecute the invention of Group I, Claims 1-9. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

2. Claim 8 is objected to because of the following informalities: The compounds that are disclosed in instant Claim 8 are not clearly written. The "2" in the group "B(OH)2" should be a subscript. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for RCOOH groups, does not reasonably provide enablement for RCOOH groups that are nonsteroidal anti-inflammatory drugs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant fails to provide adequate representations of RCOOH groups that are nonsteroidal anti-inflammatory drugs. One would not expect the compounds that are represented by the RCOOH formula in the instant application to include nonsteroidal anti-inflammatory drugs. Applicant also fails to specify what heteroatoms in Claim 1 Applicants are referring to in the specification. Furthermore, no representations of the derivatives of clofibric acid or fibric acid that are indicated in instant Claim 3 have been taught, made or used in the specification. One of ordinary skill in the art would have to guess which heteroatoms and fibric derivatives Applicant's invention is intended to encompass. Therefore, based on the lack of guidance and

working examples, and the extreme breadth of the claims, one skilled in the art could not make and use the claimed invention without undue experimentation.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is not clearly stated in the claims what heteroatoms the claim intends as part of the invention.

Claim 3 is indefinite because it is not clearly stated in the claims what derivatives the claim is specifically referencing in the absense of a chemical name for the heteroatoms Applicant intends to incorporate into the composition of matter claimed, or the modification, which would facilitate a derivation from the core instantly claimed.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hertz et al ("Mode of Action of Peroxisome Proliferators as Hypolipidemic Drugs – Suppression of Apoliprotein C-III", The Journal of Biological Chemistry, Vol. 270, No. 22, Issued June 2, pp. 13470-13475, 1995).

Applicants claim a pharmaceutical composition of instant Claims 1-5. The Hertz et al reference discloses aryloxyalkanoic fibrates (*e.g.* clofibrate and bezafibrate) and substituted long chain dicarboxylic acids (*e.g.* Medica 16) that can be used in humans as drugs for treating hypertriglyceridemia or combined hypertriglyceridemia/hypercholesterolemia. The clofibrate and bezafibrate compounds embrace the clofibric acid and fibric acid or salt, ester or derivative thereof that are disclosed in instant Claim 3 and Medica 16 falls within the description of the compounds of the formula R-COOH when R represents 16 carbon atoms and is substituted by carboxyl groups. The composition of the instant claims differ from the composition of the Hertz et al reference by disclosing in the claims that the compound of formula R-COOH is capable of being endogenously converted to its respective coenzyme A thioester, RCOSCoA. This statement is a process limitation or indicates how the compound may be used. However, process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art and a difference in the intended use cannot render a claimed composition novel. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant(s) invention having the Hertz et al reference before him to replace the clofibrate, bezafibrate or Medica 16 compounds of the Hertz et al reference with closely similar clofibric acid, fibric acid or compounds of the formula RCOOH when R comprises 16 carbon atoms and substituted with carboxyl groups in view of their closely related structures and the resulting expectation of similar therapeutic properties.

9. Claims 1, 2 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Tana (US Patent No. 4,689,344).

Applicants claim a pharmaceutical composition of instant Claims 1 and 7.

The Bar-Tana patent discloses pharmaceutical compositions comprising compounds of formula I that is set forth in column 2, lines 21, wherein R_1, R_2, X and Y each may represent a methyl group (see column 2, lines 51-53) and Q can represent a linear chain of 8 to 14 carbon atoms. The above description covers the compounds disclosed in instant Claim 7. The composition of the instant claims differ from the composition of the Bar-Tana patent by disclosing in the claims that the compound of formula R-COOH is capable of being endogenously converted to its respective coenzyme A thioester, RCOSCoA, which is not indicated in the Bar-Tana patent. This statement is a process limitation or indicates how the compound may be used. However, process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art and a difference in the intended use cannot render a claimed composition novel. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant(s) invention having the Bar-Tana patent before him to replace the composition comprising the compound of formula I in the Bar-Tana patent with closely similar compositions comprising compound of the formula RCOOH when R is an alkyl chain substituted with a carboxy and methyl groups in view of their closely related structures and the resulting expectation of similar therapeutic properties.

10. Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Copper et al (US Patent No. 4,954,487).

Applicants claim a pharmaceutical composition of instant Claims 1 and 6.

The Cooper et al patent discloses pharmaceutical compositions that can comprise compounds of the formula R^3-X, where R^3 may represent straight-chain alkyl of about 7 to about 16 carbon atoms or an alkenyl of about 7 to about 22 carbon atoms, and X may represent the symbols disclosed in column 3, lines 26-40, that include –COOR4 where R4 may be –H, or ester and amide groups thereof. Examples of these compounds disclosed by the Cooper et al patent in the last paragraph of column 3 include the compounds methyl and ethyl esters of n-dodecanoic and hexadecanoic acid; the methyl and ethyl amides of n-octanoic, decanoic, dodecanoic, tetradecanoic

and hexadecanoic acids; oleic; linolenic; oleate; and linolenate, which are a few of the compounds that embraces the compounds disclosed in the instant claims. Cooper et al also discloses nonsteroidal anti-inflammatory agents that can be used in the composition thereof that appear to embrace the nonsteroidal anti-inflammatory drug of instant Claim 4. The composition of the instant claims differ from the composition of the Cooper et al patent by disclosing in the claims that the compound of formula R-COOH is capable of being endogenously converted to its respective coenzyme A thioester, RCOSCoA, which is not indicated in the Cooper et al patent. This statement is a process limitation or indicates how the compound may be used. However, process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art and a difference in the intended use cannot render a claimed composition novel. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant(s) invention having the Cooper et al patent before him to replace the composition comprising the compound of the formula R^3-X in the Cooper et al patent with closely similar compositions comprising compound of the formula RCOOH when R is designated as a saturated or unsaturated alkyl chain in view of their closely related structures and the resulting expectation of similar therapeutic properties.

11. Claims 1, 2, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al (US Patent No. 5,502,226).

Applicants claim a pharmaceutical composition of instant Claims 1, 2, 8 and 9.

The Cho et al patent discloses ω-hydroxyl acids that may be used in skin treatment and cosmetic compositions. See examples of the ω-hydroxyl acids beginning in column 6, line 55 which include 16-hydroxy hexadecanoic acid and 18-hydroxy octadecanoic acid. The composition of the instant claims differ from the composition of the Cooper et al patent by disclosing in the claims that the compound of formula R-COOH is capable of being endogenously converted to its respective coenzyme A thioester, RCOSCoA, which is not indicated in the Cho et al patent. This statement is a process limitation or indicates how the compound may be used. However, process limitations cannot impart patentability to a product that is not patentably distinguished

over the prior art and a difference in the intended use cannot render a claimed composition novel. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant(s) invention having the Cho et al patent before him to replace the composition comprising the ω-hydroxyl acids in the Cho et al patent with closely similar compositions comprising compound of the formula RCOOH when R is designated as a ω-hydroxyl chain in view of their closely related structures and the resulting expectation of similar therapeutic properties.

Summary

12. Claims 1-9 are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

13. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at **www.uspto.gov** and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

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JAMES O. WILSON
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